Exhibit 1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Mika JOKINEN et al.

Serial Number: 09/913,643 Group Art Unit: 1618

Filed: October 19, 2001 Examiner: Fubara, Blessing M.

For: BIODEGRADABLE CERAMIC FIBRES FROM SILICA SOLS

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Mika Jokinen, declare and state:

1. I am the Research Director of DelSiTech Ltd., the owner of U.S. Patent Application S.N. 09/913,643 (hereinafter "this application").

2. I have been awarded various degrees in Chemical Engineering, including a Master of Science in 1993, a Licentiate of Technology in 1998 and a Doctor of Science in Technology in 1999. A copy of my resume is attached as Exhibit 1.

3. I am one of the inventors of the invention described and claimed in this application. Claims 24-33 are pending, and are directed to a biodegradable silica fibre spun from silica sol, the fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h, and a delivery device, pharmaceutical preparation and a method for administering a biologically active agent to a human or animal, all based on the fibre.

4. The 0.2 to 20 wt-%/h solubility rate range of the claimed fiber means it dissolves very quickly in simulated body fluid - at the slowest solubility rate of 0.2 wt-%/hour, the claimed fiber will dissolve completely within 21 days.

5. The solubility rate of the claimed silica fiber in simulated body fluid is important because this *in vitro* property can be correlated with the fiber's dissolution rate achieved *in vivo* (biodegradability). It is important to understand that solubility measured as saturation level is not that important *in vivo* because the body liquid dissolved into (typically interstitial fluid) is constantly being renewed. Accordingly, saturation is most often not an issue.

6. I am aware claims 24-33 of this application have been rejected as obvious to one of ordinary skill in the art over PCT Patent Publication WO 97/45367 to Ahola et al. (hereinafter "Ahola et al.").

7. Example 2 of Ahola et al. reports that silica fibers spun from a sol were put into aqueous solution within 48 hours and also four months later. Additional fibers were treated at 300°C and 700°C in addition to the fibers kept at room temperature. These fibers were dissolved in either a tris-methylaminomethane HCl buffered aqueous solution or a simulated body fluid solution. Importantly, only fibers kept at room temperature dissolved in any significant amounts.

8. Ahola et al. report their room temperature fibers stored for four months dissolved by 10 wt-% within four weeks. These "room temperature" silica fibers had a

solubility rate in simulated body fluid of 0.0149 wt-%/hr, which is significantly less than the 0.2 to 20 wt-% solubility rate required by claims 24-33.

9. The Patent Office appears to argue the biodegradability of a silica fiber is inherent or based solely on its chemical composition (Official Action, page 12, last paragraph). However, the solubility rate of a silica fiber is not inherent to the chemical composition of the fiber per se. Instead, a silica fiber's solubility rate in simulated body fluid is determined, at least partly, by the specific processing parameters the fiber experiences during the spinning process.

10. Example 2 of Ahola et al. demonstrates that its silica fibers' solubility rate in simulated body fluid is not an inherent property, but is instead determined at least partially by processing parameters such as heat treatment. If solubility rate was an inherent property of silica fibers based only on chemical composition, then all of the fibers of Example 2 would have the same solubility rate. The factual showing of Example 2 of Ahola et al. demonstrates this is not the case - some of the Ahola et al. fibers dissolved and some (most) of them did not. Thus, their solubility rates were not the same.

11. I am aware claims 24-33 of this application have also been rejected as obvious to one of ordinary skill in the art over German Patent Publication 196 09 551 (hereinafter "German '551"). 12. The English language translation of German '551 discloses biologically degradable and/or biologically resorbable fibers and a method for their preparation in which the fibers are obtained by partial or complete

hydrolytic condensation of one or more hydrolytically condensable silicon compounds and/or precondensates derived therefrom. The hydrolytic precondensation is performed in water and eventually in the presence of a catalyst and/or a solvent and preferably according to a sol-gel method. The hydrolytic condensation produces a spinning mass from which continuous, long and/or short fibers can be prepared according to conventional methods.

13. The claimed fiber has a solubility rate in simulated body fluid of from 0.2 to 20 wt-%/hr. German '551 does not disclose or suggest this solubility rate range, which will result in complete fiber dissolution in about 21 days for the lower (slower) dissolution range limit. Instead, German '551 discloses a fiber whose fastest dissolution time is 50 days.

14. In my opinion, the prior art does not disclose or suggest a rapidly dissolvable silica fiber for at least two reasons. First, before the present invention it was not known the solubility rate of silica fibers would increase if the fibers were spun from sols of higher viscosities. Accordingly, there was no motivation or reason to spin fibers from sols having a high viscosity. Second, it was known that the viscosity of a silica sol increases over time, and that processing problems relating to gelation of the sol prior to completion of drawing of the fiber could be encountered when spinning fibers from sols of very high viscosities. Thus, those of ordinary skill in the art possessed a reason to avoid the use of high viscosity silica sols to spin fibers.

15. In my opinion, one of ordinary skill in the art would consider the fast solubility rate of the claimed fiber to be unexpected and surprising in view of both Ahola et al. and German '551. At the time of this invention, fibers with such fast solubility rates had not been achieved, despite the fact that the prior art employed much the same process steps (except for controlling the viscosity of the silica sol from which the fiber is spun). Accordingly, one of ordinary skill in the art would not have believed a biodegradable silica fiber could be made having a solubility rate in simulated body fluid such that the entire fiber would dissolve in less than 21 days.

16. In conclusion, I do not believe either Ahola et al. or German '551 raise a prima facie case of obviousness against the claimed silica fiber because neither reference suggests how to make a rapidly dissolvable silica fiber having a solubility rate in simulated body fluid of from 0.2 to 20 wt-%/hr. In my opinion, the speed at which the claimed fiber dissolves in simulated body fluid would be surprising and unexpected because fibers with such fast solubility rates simply did not exist, and because those of ordinary skill in the art did not know how to make such fibers.

17. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that further these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false

statements may jeopardize the validity of the application or any patent resulting therefrom.

Signed this 12. day of June, 2007.

By: _____
Mika Jokinen

Exhibit 1:
Resume of Dr. Mika Jokinen

Mika Jokinen, DSc
Research Director, Adjunct Professor

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PERSONAL INFORMATION

Mika Juhani Jokinen, b. 30th September 1965 (Turku, Finland)

EDUCATION, THESES & DEGREES

Master of Science in Technology (Chemical Engineering; Industrial Chemistry) Sept. 1993
Master's Thesis," Reactions of n-Butane on ZSM-5 Catalysts, Åbo Akademi University, Faculty of Chemical Engineering, Laboratory of Industrial Chemistry, 1993.

Licentiate of Technoloy (Chemical Engineering; Physical Chemistry) April 1998
Licentiate Thesis, "Colloidal Structures of Sol-Gel Derived Bioceramics", Åbo Akademi University, Department of Physical Chemistry, 1998.

Doctor of Science in Technology (Chemical Engineering; Physical Chemistry) June 1999
Doctoral Thesis, "Bioceramics by Sol-Gel Method: Processing and Properties of Monoliths, Films and Fibres", Åbo Akademi University, Department of Physical Chemistry, 1999.

Adjunct Professor (Medical Biomaterials), February 2003
Åbo Akademi University, Faculty of Chemical Engineering & Department of Physical Chemistry

WORKING EXPERIENCE & MAIN TASKS

CURRENT POSITIONS

- **DelSiTech Ltd since 1/2006**
  - **Research Director**

- **Åbo Akademi University since 2/2003**
  - **Adjunct Professor (Medical Biomaterials)**

EARLIER POSITIONS AT UNIVERSITIES

12/1992-06/1993& 09/1993-03/1994: Åbo Akademi University, Lab. of Industrial Chemistry
- **Research assistant** (development of nanoporous aluminium silicate-based catalysts (ZSM) for alkane and NO_x conversion) and hour-based teacher

04/1994-08/1999: Åbo Akademi University, Department of Physical Chemistry
- **Researcher** & PhD student (development of sol-gel derived SiO_2-& TiO_2-based biomaterials)

- 06/1999-12/2005: University of Turku, Department of Prosthetic Dentistry and Biomaterials Research & Turku Biomaterials Centre

- Research Scientist 06/1999 - 06/2000
- Senior Scientist 07/2000-12/2005

- Research on bioceramics (SiO_2, TiO_2, bioactive glass) & bioceramic-polymer composites for tissue repair applications, drug delivery and gene therapy
- Research instructor/supervisor for 5 PhD Students and 2 other postgraduate researchers:
  - Niko Moritz (11.11.2005), Marju Väkiparta (9.12.2005) and Reeta Viitala (16.12.2005) already defended their theses and received their PhD
- Research coordinator / responsible leader in several (>10) TEKES (National Technology and Innovation Agency of Finland)-funded, large interdisciplinary projects on biomaterials (bioceramics, polymer-bioceramic composites, drug & gene delivery)
- Member of a Center of Excellence Research Group (Academy of Finland): Bio- and Nanopolymers 01/2002-12/2005; bioactive composites of polymers and bioceramics & nanoscale modification of biomaterial surfaces

EARLIER POSITIONS IN COMPANIES & COMPANY-financed PROJECTS

Turun Eko-Vesi Oy (Ltd) 08/1994-02/1996:
- Part-time project engineer (water purification by electroflotation technique)

Bioxid Oy Ltd / DelSiTech Ltd: 03/2001-09/2002 + occasionally 9/2002-8/2004:
- Part-time Research Instructor (SiO_2-based biomaterials in delivery of biologically active agents (small drug molecules, proteins)

08/2004-12/2005 —Firm-financed project (DelSiTech Ltd), Turku Biomaterials Centre
- Part-time (25%) Research Instructor (SiO_2-based biomaterials in delivery of viruses for gene therapy & encapsulation of polymeric nanoparticles in SiO_2)

10/2005-12/2005 —Firm-financed project (StickTech Ltd), Turku Biomaterials Centre
- Hour-based consultation: evaluation of scientific results on fiber-reinforced composites for dental applications & recommendation for future actions

SCIENTIFIC PUBLICATION SUMMARY (updated June, 2007)
(Publications on silica & other (bio)ceramics, sol-gel technology and biomaterials):

- International papers with referee-practice (peer-reviewed): 25 published/in press, 1 submitted
- International Letter- & Proceedings -type publications: 13 published (9 full paper-refereed)
- Patents/ Patent Applications: 8
- Abstracts in International Conferences (35 of which 22 published as abstracts and 13 as proceedings papers as indicated above): 22

Subtotal: 69

- Other publications: 21 (abstracts/short papers in domestic seminars in Finland)

Total: 90